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10/580,863

05/26/2006

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

11/23/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/580,863 | OBAE ET AL. | |
| | Examiner | Art Unit | |
| | Ganapathy Krishnan | 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-19 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-19 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/15/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed 7/2/2009 has been received, entered and carefully considered. The following information has been made of record in the instant amendment:

1. Claims 9 and 20 have been canceled.
2. New Claim 26 has been added.
3. Claims 1, 12-18, 21 and 24-25 have been amended to recite limitations regarding specific non-reducing sugars.
4. Remarks drawn to rejections under 35 USC 112, first paragraph, 102 and 103.

The following rejection of record has been overcome:

1. The rejection of Claims 9 and 20 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been rendered moot by cancellation of the said claims.

Claims 1-8, 10-19 and 21-26 are pending in the case.

The following rejection is made of record necessitated by amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 10-19 and 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Independent claims 1 and 12 recite the limitation, 'wherein the non-reducing sugar is selected from' and further recite sugars that are reducing sugars. The terms tetrose and pentose are broad are inclusive of sugars having four and five carbons that are reducing sugars. It is not clear what applicants intend. For the purpose of prosecution the claims are examined as being drawn to a beta glucan wherein a non-reducing sugar is chemically bound to the beta glucan.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 1-3, 5, 7, 10-14, 16, 18 and 21-22 under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al (Int. J. Biol. Macromol. 1995, 17(6), 373-79) is being maintained for reasons of record and is reiterated below.

Kobayashi et al teach a beta glucan oligosaccharide wherein four glucose residues are chemically attached to the fifth sugar unit, a non-reducing sugar, via an ether bond (page 375, Scheme 4, the oligosaccharide in the middle). The fifth sugar moiety on the right of the chain has a OMe (methoxy) group at the anomeric carbon, which cannot open up to reveal an aldehyde or a ketone that would reduce Fehlings solution. This teaching of Kobayashi is seen to meet the limitations of the said instant claims.

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Response to Applicants Arguments Regarding the Rejection under 35 USC 102

Regarding the rejection of 1-3, 5, 7, 10-14, 16, 18 and 21-22 under 35 USC 102 applicants have traversed the rejection arguing that independent claims 1 and 12 have been amended to recite specific non-reducing sugars. Kobayashi discloses derivatives wherein the non-reducing sugar is a hexose having a terminal OMe group at the C-1 position. The amended claims do not include such a hexose and are hence not anticipated by Kobayashi.

Applicants' arguments have been considered but are not found to be persuasive. Amended claims 1 and 12 are drawn to a beta glucan having glucose residues and a non-reducing sugar chemically attached to the beta glucan but further recites specific reducing sugars in the Markush group. The claim is interpreted as being drawn to a beta glucan wherein a non-reducing sugar is chemically bound to the beta glucan. Kobayashi's example (as above) is a glucose oligomer having more than three glucose residues (glucose is a beta glucan) to which a non-reducing sugar is chemically bound. Kobayashi's teaching meets the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of Claims 4, 6, 8, 15, 17, 19 and 23-26 under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al (Int. J. Biol. Macromol. 1995, 17(6), 373-79) in view of Koki et al (EP 0470331) is being maintained for reasons of record and is reiterated below.

Kobayashi's teaching is as above. In addition to the above, Kobayashi teaches the transfer of a non-reducing sugar to an oligosaccharide having beta-glucan residues via the action of an enzyme. Kobayashi, however, does not teach the transfer of a fructosyl group and the use of beta-fructofuranosidase enzyme for the transfer in his process.

Koki et al, drawn to fructose containing oligosaccharides, teach the use of beta-fructofuranosidase enzyme for the transfer of the fructosyl group to mono and oligosaccharides

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(see page 2, lines 55-57 and Examples). The enzyme can be used to transfer the fructosyl group to various kinds of mono- and oligosaccharides in the presence of sucrose.

Instant claim 26 is drawn to a process wherein there is a hydroxyl group at the C-1 position of the beta glucan and the transglycosylation of a non-reducing sugar is at the C-1 position of the beta glucan. It can be seen that in Kobayashi's process glycosylation occurs at the sugar unit that has a free hydroxyl group (acceptor). So, one of ordinary skill in the art will recognize that if the sugar unit does not have an OMe group at the C-1 (anomeric position) the same transglycosylation can happen there too. A minor adjustment in the structure of the beta glucan is needed to carry out the process as instantly claimed and such a modification will be recognized by one of ordinary skill in the art and is also well within the skill level of the artisan.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the beta glucan derivatives and their pharmaceutical compositions as instantly claimed via the method as instantly claimed since such a process using an enzyme is seen to be taught in the prior art using analogous oligosaccharides and non-reducing sugars.

One of skill in the art would be motivated to make the beta glucans and the pharmaceuticals as instantly claimed since the process taught by the prior art is efficient and very specific for the transfer of the fructosyl group using fructofuranosidase and has broad receptor specificity as taught by Koki et al (page 2, lines 55-57), This would allow for the transfer of a non-reducing sugar to different types of residues via a mild process. One of skill in the art would expect the process to work for other oligosaccharides and would want to make polysaccharide and oligosaccharides and their compositions since they are taught to be useful glycosides that have physiological activities (Koki, page 2, lines 1-9) and their potential as polymeric drugs and

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biomaterials (Kobayashi, page 373, left column, second paragraph). The use of enzymes also gives stereo and region control which are hard to achieve using conventional methods (Kobayashi page 373, left column, second paragraph). It is well within the skill level of the artisan to extend this method for making several different oligo and polysaccharides.

Response to Applicants Arguments Regarding the Rejection under 35 USC 103

Regarding the rejection of 4, 6, 8, 15, 17, 19 and 23-25 under 35 USC 103 applicants have traversed the rejection arguing that:

1. As an example a beta glucan Koki only describes a product produced from cellobiose having two glucose residues as a substrate. Koki does not describe the usefulness of a product in which a fructose is bound to a beta glucan having three or more residues.

2. Although Koki describes a beta-fructofuranosidase the reference does not describe or suggest using the enzyme for a beta glucan having three or more glucose residues.

Applicants' arguments have been considered but are not found to be persuasive.

Koki's process is shown to work with two glucose residues. One of ordinary skill in the art would expect the same process steps to work with a beta glucan having three or more glucose residues too. Applicants have not presented any evidence that the said process of Koki will not work for a beta glucan having three or more glucose residues. One of skill in the art would expect the process to work for other oligosaccharides and would want to make polysaccharide and oligosaccharides and their compositions **since they are taught to be useful glycosides that have physiological activities** (Koki, page 2, lines 1-9) **and their potential as polymeric drugs**

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and biomaterials (Kobayashi, page 373, left column, second paragraph). This is the usefulness of such products. One of skill in the art would look for other such products. The use of enzymes also gives stereo and region control which are hard to achieve using conventional methods (Kobayashi page 373, left column, second paragraph).

Conclusion

Claims 1-8, 10-19 and 21-26 are rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ganapathy Krishnan/

Examiner, Art Unit 1623

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623